Message Text

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PAGE 01 STATE 146152 ORIGIN ABF-01

INFO OCT-01 EUR-12 ISO-00 /014 R

DRAFTED BY A/BF/OAG:JHSOUTHERLAND:STP APPROVED BY A/BF/OAG:JHSOUTHERLAND -----129235 091033Z /20

R 082358Z JUN 78
FM SECSTATE WASHDC
TO AMEMBASSY STOCKHOLM
INFO AMEMBASSY BONN
AMEMBASSY THE HAGUE
AMEMBASSY OSLO
USMISSION USBERLIN AMSTERDAM

UNCLAS STATE 146152

AMCONSUL FRANKFURT

FRANKFURT FOR GAO EDER

E.O. 11652: N/A

TAGS: AGAO, ESCM

SUBJECT:GAO REVIEW: "NEW DRUG DEVELOPMENT AND APPROVAL PROCESS"

REF: A) STOCKHOLM 02234; B) STATE 138030

- 1. UNFORTUNATELY, BECAUSE OF TIME AND SCHEDULING CONSTRAINTS, IT WILL NOT BE POSSIBLE TO ADJUST EUROPEAN VISITS AND GAO TEAM MUST MAINTAIN ITINERARY OUTLINED PARA 6 REFTEL. B.
- 2. THE GAO WOULD APPRECIATE EMBASSY'S ASSISTANCE IN ARRANGING APPOINTMENTS ON JULY 3 OR 4 WITH THE DEPUTY TO PROFESSOR AKE LILJESTRAND AND PROFESSOR HOLGER UNCLASSIFIED

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LUNDBACK IN ORDER TO HAVE BENEFIT OF SWEDISH GOVERNMENT VIEWS ON NEW DRUG DEVELOPMENT AND APPROVAL PROCESS. IN ADDITION, THE GAO WOULD LIKE TO MEET WITH APPROPRIATE PERSONNEL IN THE DEPARTMENT OF DRUGS AND NATIONAL BACTERIOLOGICAL LABORATORY FOR DISCUSSIONS ON HOW THE SWEDISH GOVERNMENT LABORATORY PROCEDURES FIT INTO DRUG REVIEW. THE GAO TEAM WISHES TO TALK TO PERSONS INVOLVED

IN THE DAY-TO-DAY REVIEW OF NEW DRUGS TO OBTAIN AN UNDERSTANDING OF FACTORS SUCH AS WORKLOAD, PRIORITY SYSTEMS, EXTENT OF REVIEW, AND ACCEPTANCE OF FOREIGN CLINICAL AND ANIMAL TEST DATA. THESE MEETINGS COULD BE SET UP FOR JULY 5, 6 OR 7TH.

3. THE GAO TEAM WOULD UTILIZE REMAINING AVAILABLE TIME IN MEETINGS WITH REPRESENTATIVES OF ORGANIZATIONS SHOWN IN PARAS C THROUGH F OF PARA 2 REFTEL. A. VANCE

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Message Attributes

Automatic Decaptioning: X Capture Date: 01 jan 1994 Channel Indicators: n/a

Current Classification: UNCLASSIFIED

Concepts: DRUGS Control Number: n/a Copy: SINGLE Draft Date: 08 jun 1978 Decaption Date: 01 jan 1960 Decaption Note: Disposition Action: n/a Disposition Approved on Date: Disposition Case Number: n/a Disposition Comment: Disposition Date: 01 jan 1960 Disposition Event:

Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1978STATE146152
Document Source: CDR

Document Unique ID: 00 Drafter: JHSOUTHERLAND:STP

Enclosure: n/a Executive Order: N/A Errors: N/A

Expiration:

Film Number: D780241-0402

Format: TEL From: STATE

Handling Restrictions: n/a

Image Path: ISecure: 1

Legacy Key: link1978/newtext/t19780679/aaaacqls.tel

Line Count: 71 Litigation Code IDs: Litigation Codes:

Litigation History: Locator: TEXT ON-LINE, ON MICROFILM Message ID: d8fec58c-c288-dd11-92da-001cc4696bcc Office: ORIGIN ABF

Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a

Page Count: 2
Previous Channel Indicators: n/a Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: 78 STOCKHOLM 2234, 78 STATE 138030

Retention: 0

Review Action: RELEASED, APPROVED Review Content Flags:

Review Date: 29 mar 2005 Review Event: Review Exemptions: n/a **Review Media Identifier:** Review Release Date: N/A

Review Release Event: n/a **Review Transfer Date:** Review Withdrawn Fields: n/a

SAS ID: 2428016 Secure: OPEN Status: NATIVE

Subject: GAO REVIEW: \"NEW DRUG DEVELOPMENT AND APPROVAL PROCESS\"

TAGS: AGAO, SW, US To: STOCKHÓLM

Type: TE

vákvgwkey: odbc://SAS/SAS.dbo.SAS_Docs/d8fec58c-c288-dd11-92da-001cc4696bcc

Review Markings: Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014

Markings: Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014